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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,487	01/04/2002	Nannette M. VanAntwerp	PD-0268 DIV 2	6491

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/038,487	VANANTWERP ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

1. This office action is in response to the reply filed on 4/30/2007.

2. In the reply, the applicant amended claims 53 and 59 to obviate the claim objection as lacking proper antecedent basis. Thus, claims 36-59 are pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 36-39, 41-44, 46-51, 53-56, 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teissen-Simony (5522803).

5. Teissen-Simony discloses an insertion set (Fig 1) having a mounting base (1); an infusion tubing (4), wherein the infusion tubing includes a connector (3) fixedly attached to one end of the infusion tubing; wherein the infusion tubing is adapted for delivering fluid through the connector to the insertion set (Figs 1-16; Summary); a cannula (2) coupled to the mounting base (Fig 2, 5), wherein the cannula has a distal end protruding from the mounting base (2, Fig 2, 5); the cannula is in fluid communication with the infusion tubing (Figs 1-16; Summary); an insertion needle (51) having a distal end protruding from the mounting base (Fig 15, 16), wherein the insertion needle surrounds the inside of the cannula (51, 2, Fig 15, 16), and the insertion needle is withdrawable

from the mounting base after the cannula is placed at the selected insertion site (Fig 15, 16; col 6, lns 31-62); and an adhesive patch (col 2, lns 29-31) attached to an underside surface of the mounting base; and wherein the at least one lumen of the cannula is also adapted for withdrawing fluid from the patient (5, Summary; wherein the Examiner notes that the device is fully capable capable of being attached to a syringe or pump that is fully capable of creating a suction within infusion tubing and thus the cannula resulting in a withdrawal of fluid).

6. Furthermore, Teissen-Simony discloses the connector having a pair of resilient latch arms; and the mounting base includes a pair of recesses (Fig 8, 27, 28) adapted for snap-fit and releasable engagement with the pair of resilient latch arms on the connector (Fig 13, 31, 33, 32, 34).

7. However, Teissen-Simony does not expressly disclose the connector having a pair of recesses adapted for coupling the infusion tubing to the insertion set; and the mounting base includes a pair of resilient latch arms rearwardly projecting from the mounting base and adapted for snap-fit, releasable engagement with the pair of recesses on the connector. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the resilient latch arms provided on the connector and the recesses provided on the mounting base as taught by Teissen-Simony with the visa versa wherein the resilient latch arms are provided on the mounting base and the recesses are provided on the connector since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

8. Claims 40, 45, 52, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teissen-Simony in view of Lord et al (5390671). Teissen-Simony discloses the invention substantially as claimed except for wherein the cannula further includes at least one lumen for receiving at least a portion of a flexible sensor, the sensor having a distal segment protruding from the mounting base with at least one sensor electrode. Lord et al teaches that it is known to have wherein the cannula further includes at least one lumen for receiving at least a portion of a flexible sensor therein, the sensor having a distal segment protruding from the mounting base (Figs 1-3) with at least one sensor electrode for the purpose of easily placing a sensor on a patient with the sensor electrodes in direct contact with patient blood so that appropriate blood chemistry readings can be taken. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor as taught by Teissen-Simony with the sensor as taught by Lord et al for the purpose of easily placing a sensor on a patient with the sensor electrodes in direct contact with patient blood so that appropriate blood chemistry readings can be taken.

Response to Arguments

9. Applicant's arguments filed 4/30/2007 have been fully considered but they are not persuasive.

10. The Applicant argues against the 35 USC 103(a) rejection to Teissen-Simony as being an obvious reversal. Specifically, the Applicant argues:

i. "The Examiner agreed with the contention of the Applicants' representative, but also required a submission of a more detailed response that would allow the Examiner to conduct a new search" (Remarks, pg 9, paragraph 2)

ii. "It is easier for the patient to hold the mounting base and maneuver the latch arms(s) on the mounting base because the mounting base is stabilized on the patients skin. Such a latch mechanism ... is especially useful for patients with dexterity problems" (Remarks, pg 10, paragraph 2)

iii. "An important advantage of the claimed design ... is providing ease of use for patients with dexterity problems... patients with dexterity problems would find it difficult to utilize the infusion set described in Teissen-Simony because pressing in the latch arms on the freely moving connector might potentially cause the infusion set to be dislodged" (Remarks, pg 10, paragraph 4)

iv. Other considerations must be observed to assure a safe and usable device, including exposing the latch arms and/or needle to potentially snagging on pieces of clothing and exposing the needle on the connector to the possibility of inadvertent pricing (Remarks, pg 11, paragraph 2).

11. In response to applicant's argument that (i), the Examiner notes that this is not correct (see Examiner Interview Summary Record mailed 4/12/2007, pg 4). The Examiner merely agreed to consider the Applicant's arguments in a full response

specifically centering on arguments of the advantages of having the resilient latch arms on the mounting base and reasons why the Applicant believes it would not be obvious to reverse the resilient latch arms and recesses of Teissen-Simony. The Examiner notes that the Applicant's response on 4/30/2007 appears to lack any arguments against the obviousness of reversing the resilient latch arms and recesses of Teissen-Simony.

12. Rather, the Applicant appears to be solely focusing on secondary considerations as shown in arguments (ii-iv) including supposed benefits and unexpected results of the Applicant's invention. In lieu of this fact, the Examiner notes when considering secondary consideration the weight attached to the evidence of secondary considerations will depend on the relevance to the issue of obviousness and the amount and nature of the evidence (MPEP 716.01(b)). To be given substantial weight any objective evidence should be supported by actual proof and facts provided by expert affidavits (MPEP 716.01(c)). The secondary evidence present by the Applicant is not sufficient declarative evidence to be considered with substantial weight (see MPEP section 716).

13. Furthermore, the Examiner additionally notes in regards to (ii) some of the independent claims (1, 48) do not have an adhesive patch and therefore do not claim stabilization of the mounting base on the skin by an adhesive.

14. Furthermore, the Examiner additionally notes in regards to (iv) that the needle need not be exposed to inadvertent pricking because as shown in Fig 13 the guide pins (21, 22) remain to shield the needle from inadvertently pricking the skin.

15. The light of the arguments (i-iv) and evidence provided by the Applicant, Examiner maintains that one of ordinary skill in the art would find it obvious to merely reverse the resilient latch arms and recesses because such a reversal involves only routine skill in the art. The rejection is maintained.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Suzuki et al (4682981); Marggi (6302866); Bierman (6224571); Murphy (6450973); Steg (6488663).

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER